IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA

ROSE M. BALLARD and ALANA NEWTON, Individually and as Co-Personal Representatives of the ESTATE OF JIMMY BALLARD, Deceased,	)	
Plaintiffs,	)	
v.	)	Case No. 14-CV-404-GKF-FHM
JOHNSON & JOHNSON a/k/a JOHNSON & JOHNSON, INC. a/k/a JOHNSON & JOHNSON COMPANY, JANSSEN PHARMACEUTICA PRODUCTIONS, LP, ALZA CORPORATION, MYLAN PHARMACEUTICALS, INC. and MYLAN, INC.	)	
Defendants.	)	

OPINION AND ORDER

Before the court is the Motion to Dismiss [Dkt. #16] of defendants Mylan Inc. and Mylan Pharmaceuticals Inc. ("Mylan"), filed pursuant to Fed. R. Civ. P. 12(b)(6). Mylan contends plaintiffs' claims are barred by applicable statutes of limitation; plaintiffs have failed to plead their fraud claim with sufficient particularity; and federal law preempts all claims challenging the adequacy of Mylan's warnings. Plaintiffs Rose M. Ballard and Alana Newton oppose the motion.

I. Background/Procedural Status

Plaintiffs allege that Jimmy Ballard ("Ballard") died in November 2005 due to defects in a fentanyl patch. On November 2, 2007, plaintiffs filed a Petition in Creek County, Oklahoma District Court against Johnson & Johnson Company, Janssen Pharmaceutica Productions, LP, ALZA Corporation, Dr. C. Scott Anthony, D.O., Tulsa Pain Consultants, P.C., Kathy's Pharmacy & Gifts and John Doe Defendants 1, 2, 3 and 4 (the "2007 Petition").[1] The 2007 Petition asserted claims against Johnson & Johnson, Janssen, ALZA and the John Doe defendants for (1) strict-liability design defect and failure to warn; (2) negligence; and (3) breach of express warranty and fraudulent concealment. It asserted a claim for wrongful death against all defendants. [Dkt. #16, Ex. 2, 2007 Petition]. Plaintiffs sought punitive damages against Johnson & Johnson, Janssen, ALZA and the John Doe defendants, alleging they had acted willfully, maliciously, and/or with reckless disregard for the safety of ultimate consumers of Duragesic patches. [*Id.*]. Neither Mylan nor any of its affiliates were named in the 2007 Petition.

Attached to the 2007 Petition was an amended death certificate dated May 1, 2006 and the Report of Investigation by Medical Examiner ("Report") dated April 13, 2006. [Dkt. #16, Ex. 2, Petition, Exs. A and B thereto]. In the Report, a diagram of the body showed a patch affixed to the front right side of the torso; the patch was labeled "Medication Patch Duragesic ™ 75 ug." [*Id.*, Ex. 2 at 27]. The Final Summary of the Report stated that a "fentanyl patch (75 ug/hour) is found on the body;" "[t]oxicology screening reveals the presence of fentanyl as well as valproic acid and sertraline;" "[t]he measured level of fentanyl is significantly above levels

[1] The 2007 Petition alleged "John Doe Defendants 1 and 2 may be the individuals or entities that designed, manufactured, sold, distributed or otherwise placed in the stream of commerce the patch which caused injur[i]es to Plaintiffs" and "John Doe Defendants 3 and 4 may be the individuals or entities who are otherwise responsible for or liable for the injuries to the Plaintiffs that form the basis of this petition." [Dkt. #16, Ex. 2, 2007 Petition, ¶¶6-7].

described for transdermal patches of the strength found on the body;" "[t]his level has been reported as fatal in some published cases;" "[t]he cause of death is considered to be the toxic effects of fentanyl; and "[t]he manner of death is categorized as accident." [*Id.* at 32].

Plaintiffs voluntarily dismissed the 2007 Petition on August 26, 2010. [Dkt. #7 at 14, August 26, 2011 Petition ("2011 Petition"), ¶13]. One year later, on August 26, 2011, they filed a second Petition in Creek County District Court. [*Id.* at 12-28]. The 2011 Petition named the same defendants and asserted the same claims as the 2007 Petition.

On November 8, 2012, Kathrine Dossey, the owner and chief pharmacist of Kathy's Pharmacy, was deposed. [Dkt. #27, Ex. 2, Affid. of Oleg Roytman, ¶¶4-5]. Dossey testified that on November 1, 2005, she filled decedent's October 29, 2005 prescription for Duragesic, 75 micrograms per hour TDSY by dispensing ten Fentanyl 75 microgram patches manufactured by Mylan. [Dkt. #27, Ex. 3, Dossey Dep., 21:17-22:9; 23:10-23].

On April 7, 2014, the state court entered an order permitting plaintiffs to "add additional Defendants." [Dkt. #7 at 314]. On April 25, 2014, plaintiff filed an Amended Petition, adding Mylan. [*Id.* at 29-46, Ex. 2, Amended Petition] In addition to Mylan, Johnson & Johnson, Janssen Pharmaceutica Products, LP and ALZA Corporation are named as defendants in the Amended Petition. Mylan was served with a copy of the Amended Petition on June 16, 2014, and on July 16, 2014, 2014, removed the action to federal court based on diversity jurisdiction.

II. Relevant Allegations of Amended Petition

Duragesic is the registered name for a trans-dermal patch available only by prescription. The patch contains a gel form of fentanyl, an opioid that is up to 100 times stronger than morphine. [Dkt. #7, Ex. 2, Amended Petition, ¶11]. The Duragesic and/or Fentanyl patch is

applied directly to the user's skin and is designed to deliver fentanyl medication at a regulated rate for up to 72 hours. [*Id.*, ¶12].

Plaintiffs allege that on or about November 2, 2005 Jimmy Ballard used a 75-microgram Duragesic and/or Fentanyl transdermal patch prescribed to him. The patch was manufactured, sold, distributed and placed in the stream of commerce by Johnson & Johnson, Janssen, ALZA and/or Mylan. [*Id.*, ¶13]. The patch in question was prescribed to Ballard on October 29, 2005. [*Id.*, ¶14]. Upon information and belief, Kathy's Pharmacy & Gifts filled the prescription for the patch on or about November 1, 2005. [*Id.*, ¶15]. On November 3, 2005, Ballard was found dead in his Creek County home. [*Id.*, ¶16]. A Duragesic and/or Fentanyl patch was found on the body at the time of death. [*Id.*, ¶17]. Tulsa County Medical Examiner R.F. Distefano, D.O., who performed the autopsy, found the cause of death to be "toxic effects of fentanyl." [*Id.*].

At all relevant times, Johnson & Johnson, Mylan and Janssen designed, developed, licensed, promoted, manufactured, marketed, sold and distributed pharmaceuticals and other products, including the Duragesic and/or Fentanyl patch at issue in this lawsuit. [*Id.*, ¶18]. Johnson & Johnson, Mylan and Janssen acted in conjunction with other affiliated, related, jointly owned or controlled entities or subsidiaries, including, but not limited to ALZA. [*Id.*].

At all relevant times, ALZA designed, developed, licensed, promoted, manufactured, marketed, sold and distributed pharmaceuticals and other products, including drug delivery systems such as the one used in the patch at issue in this lawsuit. [*Id.*, ¶19]. ALZA was affiliated with Johnson & Johnson and Janssen through mergers, joint venture, joint or common ownership or otherwise. [*Id.*].

Using a patented drug delivery system developed by ALZA or others, defendants designed, manufactured, distributed, sold and placed in the stream of commerce millions of

Duragesic and/or Fentanyl patches like the one in question. [*Id.*, ¶20]. In the drug delivery system, the opioid drug, fentanyl, is placed inside a patch which is designed to be placed on the skin of the user and, in theory, the drug is then introduced to the user at a controlled rate over a period of time. [*Id.*]. Thousands of defective leaking patches, which caused serious drug overdose injury and death in and outside the state of Oklahoma, were among the millions of patches placed in the stream of commerce in 2005. [*Id.*].

Ballard did not know, and could not have known, that the Duragesic and/or Fentanyl patch prescribed and sold to him was defective as a matter of law and would cause injury and death, or that defendants were aware and had knowledge that certain Duragesic and/or Fentanyl patches they manufactured, marketed, sold and distributed were *per se* defective and had the propensity to cause severe injury including death. [*Id.*, ¶¶21-22]. Defendants knew or should have known as early as October 2001 that their manufacturing processes were flawed; and such flaws included fold-overs in backing of the patch system, gel in the seal, seal breaches, corners of the patch system cut off, holes in the drug reservoir, slits in the patch's pouch and stem, no gel in the system, air bubbles in the adhesive layers of the system, and lack of adhesion in the patch system. [*Id.*, ¶23]. Defendants took inadequate steps to advise physicians, hospitals, nursing homes and consumers, including Jimmy Ballard, of this defect, the risk posed by the defects and the significant dangers presented to those using a defective Duragesic and/or Fentanyl patch. [*Id.*, ¶¶24-25]. They also failed to take adequate steps to ensure that all lots they had manufactured were safe for the public and would function in the manner in which they were intended. [*Id.*, ¶25].

The Duragesic and/or Fentanyl patch used by Ballard on or about November 2, 2005 was defective in that it exposed him to an excessive and deadly amount of fentanyl. [*Id.*, ¶26]. As a result, he received an overdose of the opioid fentanyl and died at the age of 43. [*Id.*].

Defendants were each aware of the defects in the Duragesic and/or Fentanyl patches, knew the risks and dangers such defects posed to those using the patches, and aided and abetted, ratified, authorized and acted in concert in the wrongful conduct. [*Id.*, ¶29]. They have widely promoted the use of Duragesic and/or Fentanyl patches as a safe and effective method of dealing with persistent and severe pain. [*Id.*, ¶31]. They had a duty, once they learned of any potential problems with Duragesic and/or Fentanyl patches, to adequately notify users and consumers and to promptly recall any defective or potentially defective patches, and "[t]his was obviously not done in the case at hand." [*Id.*, ¶56].

The Amended Petition alleges defendants "owed a duty to Jimmy Ballard to protect him against reasonably foreseeable harms which a prudent person would anticipate were likely to result from the Defendants' acts or omissions." [*Id.*, ¶77]. They breached that duty when they acted in a "negligent and/or tortious manner as set forth in the paragraphs above" and their conduct "was the direct and proximate cause of Jimmy Ballard's premature death." [*Id.*, ¶¶78-79].

Plaintiffs seek actual damages in excess of $75,000. [*Id.*, ¶¶52, 63, 68, 75, 82]. Further, they allege defendants acted willfully, maliciously, and/or with reckless disregard for the safety of Ballard and other ultimate consumers, and therefore, plaintiffs are entitled to recover punitive damages. [*Id.*, ¶¶84-86].[2]

[2] Plaintiffs characterize their demand for punitive damages as their Sixth Cause of Action. [*Id.*, Amended Petition at 44-45]. Under Oklahoma law, though, punitive damages do not constitute a cause of action, but are only an element of the damages recoverable in a cause of action when the proof warrants such recovery. *Smith v. Warehouse*

III. Analysis

A. Strict Liability, Negligence, Fraud and Wrongful Death Claims

Plaintiffs' claims for strict liability, negligence, fraud and wrongful death are all subject to two-year statutes of limitation. *See Kirkland v. Gen. Motors Corp.*, 521 P.2d 1353, 1361-62 (manufacturers' product liability); Okla. Stat. tit. 12, § 95(3) (tort; fraud); and Okla. Stat. tit. 12, § 1053(A) (wrongful death).

In their response to Mylan's Motion to Dismiss, plaintiffs assert their claim against Mylan did not accrue, and therefore the statute of limitations did not begin to run, until the November 8, 2012, deposition of the pharmacy's owner. Attached to plaintiffs' response are the affidavit of plaintiffs' attorney, Oleg Roytman, explaining plaintiffs' efforts to obtain pharmacy records, and excerpts from the deposition of the pharmacy's owner. [Dkt. #27, Exs. 2-3].

However, under Rule 12(b)(6), the court's duty is to determine whether the complaint itself is legally sufficient to state a claim for which relief may be granted. *Sutton v. Utah State Sch. for the Deaf & Blind*, 173 F.3d 1226, 1236 (10th Cir. 1999). In making this determination, the court "must accept all the well-pleaded facts of the complaint as true and must construe them in the light most favorable to the plaintiff." *Bauchman v. West High School*, 132 F.3d 542, 550 (10th Cir. 1997). Although dismissal is appropriate only if the plaintiffs can prove no set of facts in support of the claim entitling them to relief, "counsel may not overcome pleading deficiencies with arguments that extend beyond the allegations contained in the complaint." *Id.* Thus, plaintiffs may not rely on their attorney's affidavit and the deposition testimony of the pharmacist to correct the deficiencies in the Amended Petition.

Market, Inc., 586 P.2d 724, 726 (Okla. 1978); *Gilbreath v. Phillips Petroleum Co.*, 526 F. Supp. 657, 660 (W.D. Okla. 1980) (citation omitted).

Mylan's statute of limitations defense is established on the face of the April 25, 2014, Amended Petition, which alleges (1) decedent was found dead in his home on November 3, 2005, (2) a Duragesic or fentanyl patch was found on his body, and (3) the Tulsa County Medical Examiner determined the cause of death was "toxic effects of fentanyl." Therefore, plaintiffs' claims for strict liability, negligence, fraud and wrongful death are time-barred.

Moreover, even had plaintiffs pled the facts set forth in their attorney's affidavit, Oklahoma law does not support their position that the claims were timely filed. Oklahoma courts apply the "discovery rule" to toll the statute of limitations in tort cases "until the injured party knows or, in the exercise of reasonable diligence, should have known of the injury." *Digital Design Group, Inc. v Information Builders, Inc.*, 24 P.3d 834, 841 (Okla. 2001) (citation omitted.) As the Oklahoma Supreme Court has explained:

> The [discovery] rule . . . arises from the inability of the injured, despite the exercise of due diligence, to know of the injury or its cause. The purpose of the rule is to exclude the period of time during which the injured party is reasonably unaware tha[t] an injury has been sustained so that people in that class have the same rights as those who suffer an immediate ascertainable injury . . . .

Id. Nevertheless:

> Even under the discovery rule, a plaintiff is required to pursue claims with diligence. The statute of limitations is not tolled simply because a plaintiff negligently refrains from prosecuting inquiries plainly suggested by the facts. Accordingly, a plaintiff is charged with having knowledge of those facts which ought to have been discoverable in the exercise of reasonable diligence.

Erikson v. Farmers Group, Inc., 2005 WL 2651312, at *3 (10th Cir. Oct. 18, 2005) (unpublished) (citing *Daugherty v. Farmers Coop. Ass'n*, 689 P.2d 947, 951 (Okla. 1984) (internal quotes omitted)).

Plaintiffs argue the identity of the manufacturer could not be discovered, despite diligent efforts, until the deposition of the pharmacist. However, the discovery rule does not, as plaintiffs

urge, apply to delays in identifying the product manufacturer. Rather, it tolls the statute of limitations only "until the injured party knows, or in the exercise of reasonable diligence, should have known of the *injury*." *Resolution Trust Corp. v. Grant*, 901 P.2d 807, 813 (Okla. 1995) (emphasis in original). *See also Wells v. Lowe's Home Centers, Inc.*, 2008 WL 2783161, at *2 (N.D. Okla. July 15, 2008) (dismissing product liability claim as time barred where plaintiffs sued saw blade manufacturer more than four years after date of injury); *Wandschneider v. Tuesday Morning, Inc.*, 2011 WL 3319562, at *3 (N.D. Okla. Aug. 1, 2011) (granting manufacturer's motion to dismiss, denying as futile plaintiffs' motion to amend complaint and holding plaintiffs' claim against manufacturer was time barred because they failed to sue manufacturer within two years after date of injury caused by allegedly defective stool). Further, "[e]xceptions to statutes of limitation are strictly construed and are not enlarged on consideration of apparent hardship or inconvenience." *Resolution Trust Corp.*, 901 P.2d at 813.

Here, Ballard was found dead on November 3, 2005, and the medical examiner certified the cause of death as "toxic effects of fentanyl" on April 13, 2006. At that point, plaintiffs "knew of the injury." *Id.* The court concludes, therefore, that plaintiffs' strict liability, fraud and negligence claims against Mylan are time barred.[3]

B. Breach of Warranty Claim

"Breach of warranty claims are viable in the context of manufacturer's products liability only to the extent that a breach of warranty claim may be pursued under the Uniform Commercial Code." *Stewart v. Sulzer Orthopedics, Inc.*, 2011 WL 2491593, at *4 (N.D. Okla. June 22, 2011). Thus, plaintiffs claim for breach of warranty is subject to a five-year statute of limitations, and the statute of limitations for breach of warranty accrues upon "delivery" of the

[3] The court need not address Mylan's arguments that (1) the Amended Petition fails to satisfy Rule 9(b)'s requirement for pleading fraud with particularity and (2) plaintiffs' product liability/failure to warn claim is pre-empted by federal law.

goods, regardless of the aggrieved party's lack of knowledge of the breach. Okla. Stat. tit. 12A, § 2-725(1) and (2).

The Amended Petition alleges decedent filled the prescription for the Duragesic and/or Fentanyl patch on November 1, 2005. Therefore, the statute of limitations on plaintiffs' breach of warranty claim ran on November 1, 2010. Accordingly, the breach of warranty claim is time barred.

IV. Conclusion

For the reasons set forth above, the Motion to Dismiss [Dkt. #16] of defendants Mylan Pharmaceuticals, Inc. and Mylan, Inc. is granted.

ENTERED this 20th day of October, 2014.

GREGORY K. FRIZZELL, CHIEF JUDGE
UNITED STATES DISTRICT COURT